

### DETAILED ACTION

1. Applicant's amendment, filed 09/04/2008, has been entered.  
Claims 1-137 have been canceled.  
Claims 138-152 are currently pending.

### *Election/Restrictions*

2. Applicant's election of Invention I (claims 138-140, 145 and 151) in the reply filed on 10/29/2008 is acknowledged.

Claims 138-140, 145 and 151, drawn to the elected Invention of the antibody, appear to be allowable. Therefore, the restriction requirement between the antibody and the method of treatment using the antibody, as set forth in the Office action mailed on 09/30/2008, has been reconsidered in view of the allowability of claims to the elected invention pursuant to MPEP § 821.04(a). **The restriction requirement between the antibody and the method of using the antibody is hereby withdrawn.** The restriction requirement between the antibody and the nucleic acid is maintained.

In view of the above noted withdrawal of the restriction requirement, applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative, Lynn Apelgren on 01//07/2008.

4. Claims 141-144 and 147-150 are being **canceled**.
5. The title has been replaced with the following:  
-- HUMANIZED ANTI-IL-1 BETA ANTIBODIES --

#### **REASONS FOR ALLOWANCE**

6. The following is an examiner's statement of reasons for allowance:

Due to high polymorphism of antibodies, the anti-IL-1 beta antibodies comprising the specific heavy and light chains as recited in the present claims are deemed structurally distinct on the primary amino acid basis and therefore free from the prior art. With respect to the method claims, it is noted that IL-1 beta is known in the art to play a role in inflammation. However the prior art including references mentioned below do not teach or suggest using the particular anti-IL-1 beta antibodies as recited in the present claims to treat the arthritis. Therefore, the method claims appear to be free from the prior art.

#### **EXAMINER'S COMMENTS**

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A) Jackson et al. 1995, *Journal of Immunology*, 154:3310-3319 (citation CA on IDS) and

B) Beals et al. WO 03/073982 A2, (citation BD on IDS).

Jackson et al. taught that IL-1 beta plays a role in inflammatory diseases and that a neutralizing antibody against IL-1 beta has therapeutic values (see entire document).

Beals et al. taught using making a humanized anti-IL-1 beta antibody for treating rheumatoid arthritis or osteoarthritis (see entire document).

Taken together, the references indicate art-recognized utilities for anti-IL-1 beta antibody, i.e., treating rheumatoid arthritis or osteoarthritis.

8. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen/  
Examiner, Art Unit 1644  
January 13, 2009

/Phillip Gambel/  
Primary Examiner  
Technology Center 1600  
Art Unit 1644  
January 21, 2009